United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

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June 9, 2006

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 06-15

Subject: Request for Adjuvant and Excipient Data

To: Biologics Licensees, Permittees, and Applicants
Veterinary Services Management Team
Directors, Center for Veterinary Biologics
Area Veterinarians in Charge, VS
State Veterinarians

I. PURPOSE

The purpose of this notice is to request from all licensees, permittees, and applicants a list of all adjuvants and certain excipients currently used in production of biologics for use in food-producing animals.

II. BACKGROUND

The Center for Veterinary Biologics is updating its tracking system for adjuvants and excipients approved for use in food-producing animals. Because previous lists contain variable amounts of detail and were summarized from studies that have since been archived, we are verifying all existing data for accuracy and updating our records before they are migrated to the new tracking files. Updating these files should expedite CVB's approval of adjuvants and excipients by organizing these data into a readily accessible format. As always, these data remain confidential business information.

III. ACTION

To facilitate the update and verification of approved adjuvant and excipient data, we are requesting the cooperation of all licensees, permittees, and applicants in submitting a list of all adjuvants (i.e., vehicles intended to enhance antigenicity) currently used in the production of biological products (licensed and pending licensure) that are intended for use in food-producing animals. We are also requesting information on excipients for which residue clearance data have been generated.

Please submit the following information in a tabular format:

1. Generic name of adjuvant/excipient (and Trade Name if applicable)
2. Chemical composition of adjuvant/excipient (list of all ingredients and proportions)
   - For complex formulations, it is acceptable to cite a currently filed Special Outline containing this information.
   - For proprietary adjuvants purchased from a third party where the composition is unknown to the licensee, enter "Proprietary to <name of third-party supplier>"

3. Amount of completed/total adjuvant/excipient approved per dose of product
    - Express the amount in absolute units (e.g., mL/dose, µg/dose) rather than as a percentage relative to dose volume.
    - If the same withdrawal period has been approved for multiple products containing a variable amount of adjuvant, enter the range of concentrations approved.
4. Animal species for which adjuvant/excipient is approved
5. Route(s) of administration
6. Slaughter withdrawal time approved
7. Date of notification from the CVB that adjuvant/excipient was approved
    - This information is requested to enable the CVB to identify licensing files that contain residue clearance data.
    - If the slaughter withdrawal period was not expressly approved in subject-specific CVB correspondence, it is also acceptable to enter the original date of licensure of first product containing the adjuvant.
    - If these dates are unknown, state "Unknown"
8. Establishment number for which adjuvant was initially approved
9. All Product Code(s) in which adjuvant is currently used

In general, create one entry per adjuvant/animal species combination, provided that all uses of that adjuvant in that species have the same slaughter withdrawal period. If a particular adjuvant has different withdrawal periods for a given animal species (e.g., depending on adjuvant concentration), create separate entries to describe the circumstances for each withdrawal period.

Ideally, the data should be submitted in electronic format. A template Excel file is available on the CVB website to aid in formatting and standardizing the data submitted. Please submit these data by August 31, 2006.

/s/ Byron E. Rippke for

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics